DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PRODUCT LICENSE APPLICATION FOR RED BLOOD CELLS

Form Approved; OMB No. 0910-0124
Expiration Date: November 31, 2001.
See Reverse of Part 3 for OMB statement.

DATE SUBMITTED

NOTE: This report is mandated by Section 351 of the Public Health Service Act; the Federal Food, Drug and Cosmetic Act, Section 502 and Title 21, CFR Part 600. No license may be granted unless this completed application form has been received.

1. MANUFACTURER'S NAME, ADDRESS AND ZIP CODE	TELEPHONE NO. *(Include Area Code)*
2. ESTABLISHMENT NAME, ADDRESS AND ZIP CODE *(If different from item 1)*	TELEPHONE NO. *(Include Area Code)*

3. TYPE OF APPLICATION *(Check one)* ☐ ORIGINAL ☐ AMENDED

4. LIST LICENSE APPLICATION IS FOR:

☐ RED BLOOD CELLS ☐ AS-1 ☐ AS-3 ☐ OTHER _____
☐ RED BLOOD CELLS FROZEN*
☐ RED BLOOD CELLS, DEGLYCEROLIZED*
☐ RED BLOOD CELLS,REJUVENATED*
☐ RED BLOOD CELLS, LEUKOCYTES REMOVED BY CENTRIFUGATION*
☐ RED BLOOD CELLS, LEUKOCYTES REMOVED BY WASHING*
☐ RED BLOOD CELLS WITH ATTACHED SATELLITE OR PLASMA*

*SUMMIT A COPY OF YOUR PROCEDURE FOR PREPARING THIS PRODUCT. IDENTIFY THE SOLUTIONS AND CONTAINERS USED, INCLUDE DATING PERIOD ASSIGNED AND A LIST OF QUALITY CONTROL PROCEDURES PERFORMED.

5. DO YOU PREPARE RECOVERED PLASMA? ☐ YES ☐ NO

CERTIFICATION

I have reviewed the procedures for donor selection, blood collection, and processing in use at the time of this application and affirm that all procedures are as outlined in my Whole Blood Application filed _____.

I certify that there is documentation in the records which supports that, for each unit of the products covered in this application, all critical manufacturing steps have been performed in accordance with current Federal Regulations and that the responsible individual has signed the pertinent manufacturing records on the day of manufacture.

I also certify that all statements made in this application are true and complete to the best if my knowledge and ability. I am familiar with the pertinent Sections of Part 600-640 of Title 21, Code of Federal Regulations, and am aware of my responsibilities described therein.

WARNING: A willfully false certification is a criminal offense. U.S. Code, Title 18, Section 1001.

TYPED NAME OF RESPONSIBLE HEAD	SIGNATURE	DATE

ATTACHMENTS

A. Samples of complete labeling (including all overlays and circular* with directions for use) for all products checked in item 4. Labeling for Recovered Plasma, if applicable.

Labels should be submitted on Form FDA 2567, "Transmittal of Labels and Circulars," in triplicate and may be mock-ups or printer's proofs.

B. Procedures for preparing products checked in item 4, if applicable.

C. List of quality control procedures performed and results obtained for products identified with asterisk in item 4. For Leukocyte poor products the quality control data should include pre- and post-leukocyte counts and analysis of type of cells remaining in the product.

D. Sterility data on 10 units of frozen, deglycerolized and/or rejuvenated product, if applicable. These tests must be performed in accordance with 21 CFR 610.12 and appropriate aerobic and anaerobic positive controls must be included.

*If AABB/ARC circular is used without modification, submit one copy only.

Paperwork Reduction Act Statement:
A federal agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average .66 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to:

DHHS/PHS/FDA/Director
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